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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/408,142	09/29/1999	MASAHARU MUKOUYAMA	HIRA1140	3645

7590 08/19/2002  
LISA A HAILE  
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4365 EXECUTIVE DRIVE  
SUITE 1600  
SAN DIEGO, CA 921212189

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/19/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/408,142

Applicant(s)

Mukouyama et al

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 13, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-13, and 15-20 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-13, and 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

The amendment filed 6/13/02 is acknowledged. Claims 1-8, 10-13 and 15-20 are being considered on the merits.

The rejection under 35 U.S.C § 112, first paragraph is withdrawn in view of applicants' arguments.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for crystallization of L-aspartic acid from a suspension cooled to between 20° and 100°C. As a matter of fact, at temperatures higher than about 50°C it appears unlikely that crystallization would occur.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 8, 10 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is confusing in that it does not find proper antecedent basis in claim 1 for "mixed continuously". There is no clear "mixing" step.

Claim 8 is vague and indefinite in that the claim appears to indicate that "allowing to stand" is performed by a continuous method, which appears unlikely.

Claim 10 fails to find internal antecedent basis for "said resultant mixture". Also in claim 11 it is unclear at what point "said resultant mixture" is homogeneous. Claim 10 is also confusing in the temperature range recited. Does crystallization occur at 100°C, for example? It is apparent that L-aspartic acid is soluble at 20-30°C.

Claim 20 is vague and indefinite since the sequence of steps intended is uncertain.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, 10-13 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nore *et al.* taken with Brun *et al.*, Pavia *et al.* and Tan *et al.* for the reasons as stated in the last Office action and the further reasons below.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to Applicants' arguments that the invention can be distinguished because Nore *et al.*, for example, use an alcoholic solvent while applicants use an aqueous solution, it is noted that there is no indication that the aqueous suspension does not or may not comprise alcohol. In addition, the range of 20°C to 80°C overlaps with applicant's range of 50° to 130°C.

Applicants also argue that an alcoholic solution cannot be used with aspartase because it may cause the degeneration of the enzyme. However, there is claim designated limitation to the effect that the reactions all occurs in the same pot and that aspartase is thermostable, for example.

With regard to the cooling time and contested drop in temperature, it is noted that the arguments pertain only to dependent claim 5 wherein gradual cooling is recited and to claim 10. In addition, the significance and extent of the temperature drop is uncertain since the temperature need only drop to 100°C in some instances.

Applicant appears to rely on the gradual cooling process for crystallization purposes as the crux of the invention. Yet this seemingly critical limitation is recited in claims 5 and 10 only as noted *supra* and the manner and extent of the cooling process is not clearly delineated. The specification at page 4, paragraph 3 indicates that the rate of cooling should be between 0.1 and 5°C per minute after the addition of fumaric acid to the ammonium L-aspartate solution to

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deposit L-aspartic acid crystals of desirable purity. Does this occurs at 100°C, for example? See also the new matter rejection *supra*.

Therefore the rejection is deemed proper and it is adhered to.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

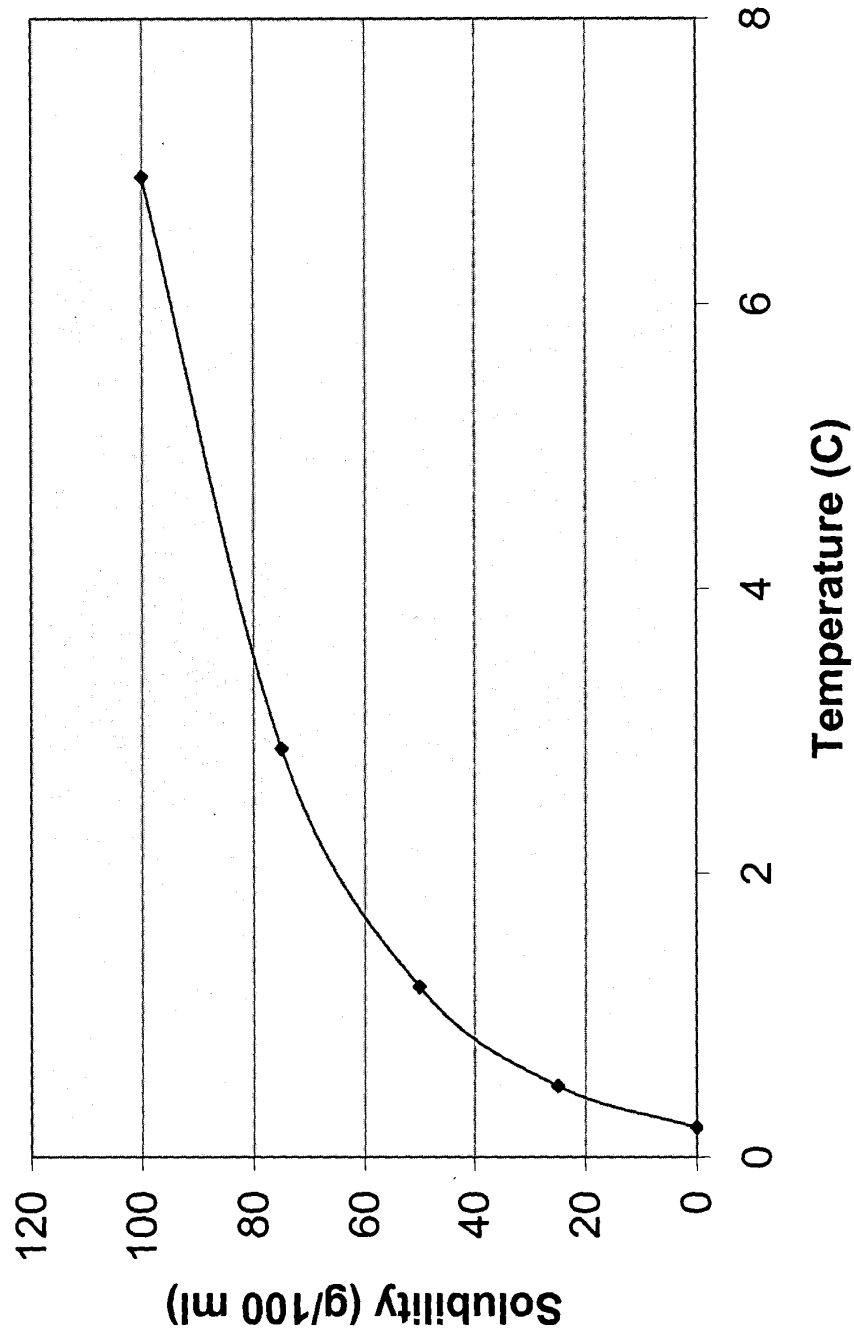
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

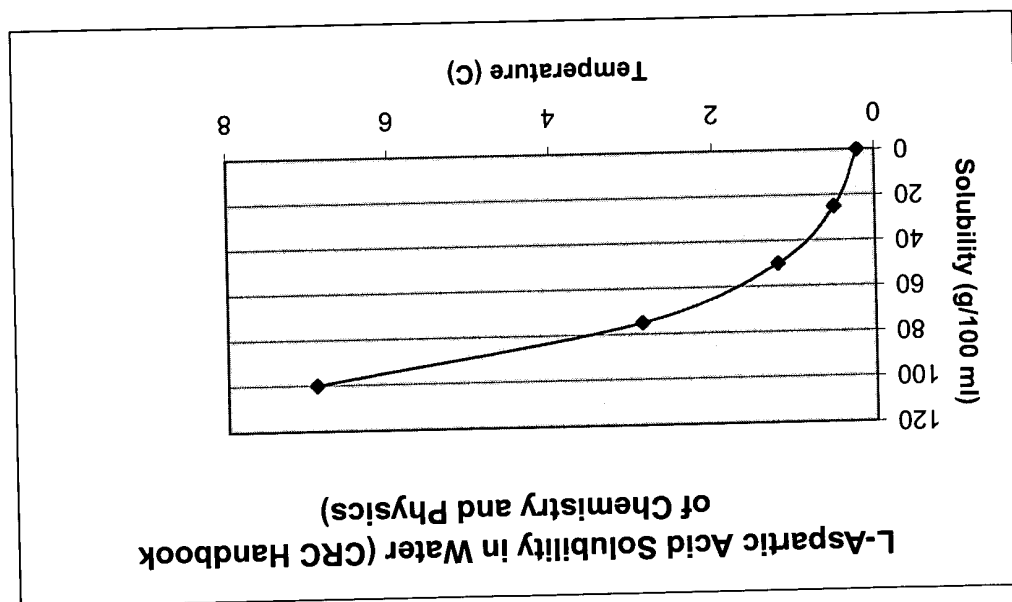
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

  
Irene Marx  
Primary Examiner  
Art Unit 1651

## L-Aspartic Acid Solubility in Water (CRC Handbook of Chemistry and Physics)





0	0.209
25	0.5
50	1.199
75	2.875
100	6.893